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EXAMINER

ULM, JOHN D

ART UNIT PAPER NUMBER

1646

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,350

Applicant(s)

LIN ET AL.

Examiner

John D. Ulm

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

- 1) Claim 13 is pending in the instant application.
- 2) Claim 13 stands objected to as reciting an improper Markush Group for those reasons of record in the previous office action.
- 3) Claim 13, in so far as it relates to any of SEQ ID NOs:4, 6, 8, 10, 14 and/or 18 is withdrawn from further consideration as being drawn to an invention that was non-elected with traverse in the correspondence filed by Applicant on 03 November of 2003. The traversal is on the grounds that a search of the different inventions in a single application would pose no serious burden because isolated proteins comprising those sequences have already been determined to be patentable. This is not persuasive because a search of the various sequences would actually entail a search of each and every epitope present in those sequences since the instant claim encompasses an antibody that binds to any epitope contained in any one of the sequences recited therein. Just because an isolated protein is patentable doesn't mean an antibody thereto is patentable. An isolated protein which differs from a prior art protein by only a single amino acid residue can be patentable over that prior art protein even though antibodies thereto clearly would not be. SEQ. ID. NO:12 and 16 will be included with the elected invention because any epitope contained therein would also be contained within SEQ ID NO:2.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 1646

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Because of the presence of the terms "comprising the amino acid sequence" "or a fragment thereof", this claim encompasses an antibody which binds to an epitope that is not contained within SEQ ID NO:2. It is old and well known in the art that the portion of a protein to which an antibody binds usually consists of no more than six to eight amino acid residues. It was also well known in the art long before the instant invention was made to express a recombinant protein as part of a fusion protein "comprising", in addition to the amino acid sequence of a desired protein, an antigenic tail such as a "FLAG epitope", a polyhistidine tail, or a "Protein A" fragment to facilitate the purification of the desired protein. Because of the presence of the term "comprising" in the instant claims, they encompass any antibody which can bind to any epitope which can be expressed as a portion of a TNF-RI-DD ligand protein comprising the amino acid sequence as set forth in SEQ ID NO:2 and, therefore this claim essentially encompasses any antibody which can bind to any polypeptide or protein. The instant specification, however, does not provide a written description or the guidance needed to produce an antibody which binds to any epitope other than an epitope which is contained within SEQ ID NO:2 of the instant application, which would include any epitope present in SEQ ID NO:12 or 16 presented therein.

Art Unit: 1646

Further, in so far as this claim recites the limitation "TNF-RI-DD ligand protein", which appears to be functionally defined, the limitation "comprising", and the limitation "a fragment thereof", which can constitute nothing more than a single amino acid residue, it is a single means claim since it encompasses any antibody which can bind to any protein having the defining activities of a "TNF-RI-DD ligand protein". A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. In re Hyatt, 708 F.2d 712, >714 □ 715, < 218 USPQ 195>, 197< (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See M.P.E.P. 2164.08(a).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claim 13 is vague and indefinite in so far as it employs the term "TNF-RI-DD ligand protein" as a limitation. Because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "TNF-RI-DD ligand protein" an artisan can not determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the

claimed subject matter by the presence of this limitation. For example, it is unclear how a claim to "an antibody which binds to a TNF-RI-DD ligand protein having the amino acid sequence of SEQ ID NO:2" differs in scope from a claim to "an antibody which binds to a protein having the amino acid sequence of SEQ ID NO:2".

6) Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the claim recites the broad limitation "SEQ ID NO:2" followed by the narrower limitations "SEQ ID NO:12" and "SEQ ID NO:16" for the same element within the same claim. Any antibody that binds to an epitope within SEQ ID NO:16 would also bind to SEQ ID NO:12 and SEQ ID

Art Unit: 1646

NO:2. However, there are numerous epitopes within SEQ ID NO:2 that are not present in SEQ ID NO:12 or 16.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –


(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7) Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by the Hopp et al. patent (5,011,912). As explained above, this claim encompasses an antibody which binds to any antigenic peptide, including the flag epitope DYKDDDDK which was bound by the antibody of Hopp et al. prior to the time of the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800